

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Tuesday, September 2, 2008, 2:00 pm – 3:00 pm ET

Minutes

I. Welcome and Introductions - call participants (listed alphabetically):

- Joan Berger, Image Solutions, Inc.
- Cheryl Blik, Teva Pharmaceuticals USA
- Chris Guay, The Procter & Gamble Company
- Jeffrey Karp, Geronmed, Inc.
- Mike Koenig, U.S. Food and Drug Administration
- John Lorenc, Reed Technology & Information Services, Inc.
- Paula Markert, GlaxoSmithKline Consumer Healthcare (co-leader)
- Andras Megyeri, Novartis Consumer Health, Inc.
- Paulette Midgette, Johnson & Johnson•Merck Consumer Pharmaceuticals Co.
- Devon Morgan, Perrigo Company (co-leader)
- Priscilla Mott, McNeil Consumer Healthcare
- Eva Rivera, Glemser Technologies Corporation
- Gary Saner, Reed Technology & Information Services, Inc.
- Barbara Spallitta, Reckitt Benckiser, Inc.
- Siobhan Stevens-Miles, Merck & Co., Inc.
- Carl Strotz, Wyeth Consumer Healthcare
- Craig Trautman, Intagras
- Marcia Howard, CHPA staff (sub-team liaison)

II. Standing Teleconference Date and Time

The standing teleconferences for the sub-team will be alternating Mondays at 1:00 pm ET (next call will be held September 15, 2008). Calls will be cancelled as appropriate.

III. Draft Guidance

There was discussion about the feedback received on the draft guidance issued by FDA. The draft guidance can be viewed at:

[http://www.fda.gov/cder/guidance/OC2008145\(2\).pdf](http://www.fda.gov/cder/guidance/OC2008145(2).pdf). The corresponding *Federal Register* notice is available at: <http://edocket.access.gpo.gov/2008/pdf/E8-15801.pdf>.

It was determined that some questions would be included in a formal response to FDA while others would be handled in the question-and-answer document. Sub-team members decided to provide feedback to the agency based as noted in the comment summary (provided as separate document).

IV. Upcoming SPL Educational Forums

- a. Drug Information Association (DIA) Webinar (September 9, 2008)
- b. DIA In-person workshop (October 29-30, 2008, in Philadelphia, PA). Please visit [CHPA website](#) for additional information, including registration materials.
- c. Generic Pharmaceuticals Association (GPhA) [Fall Technical Workshop](#) October 28, 2008, in Rockville, MD [prior to the Fall Technical Conference in Washington, DC (October 29-30)]

V. Next steps and Assignments

- A. Draft comments for the guidance document will be circulated to sub-team members by [Thursday, September 4th](#). Sub-team members should be prepared for quick review and turnaround times in order to meet the [September 9th](#) submission deadline.